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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,801	01/17/2006	Jean-Francois Garbe	3338.68US01	4287

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EXAMINER	
ADAMS, AMANDA S	
ART UNIT	**PAPER NUMBER**
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,801	GARBE, JEAN-FRANCOIS	
	Examiner	Art Unit	
	Amanda Adams	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. **Claims 10-12, 13, and 14, and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al (US 2001/0044637) in view of Suyker et al (US 6,485,496) and further in view of Sancoff et al (US 6,682,540).

2. Regarding **claims 10, 12, and 14**, Jacobs et al discloses the invention substantially as claimed including a sleeve capable of expansion between a minimal-diameter configuration and a stable expanded configuration with a series of fixation barbs arranged in a radial configuration about the proximal and distal ends and intermediate portions of the sleeve (figure 10B), wherein the sleeve is meant to be used at either end of a graft or prosthesis to connect it to a duct or vessel within the body.

3. Jacobs et al fails to disclose the sleeve being comprised of mesh, and curved barbs. However, Suyker et al teaches a mesh sleeve with diamond-shaped cutouts with a plurality of barbs located at the intersections of the diamond mesh structure, and

barbs of a curved configuration (column 3, lines 49-56). A mesh sleeve will improve the expansion capabilities of the sleeve, therefore it would have been obvious to have a mesh sleeve on the vascular device of Jacobs et al. Having curved barbs on the intermediate portion of the sleeve combined with straight barbs on the ends of the sleeve improves the sleeve's ability to engage the vessel and graft, without becoming entangled with itself upon expansion. Therefore it would have been obvious to configure the barbs in such a way wherein the intermediate barbs are curved while the other barbs are straight.

4. Additionally regarding the shape of the barbs, due to lack of criticality in the specification, the circular base and trihedral-shaped extension of the barbs were shown to solve no particular problem, serve no particular purpose, and provide no additional benefit as opposed to curved barbs or barbs of any other configuration. Therefore it would have been obvious to substitute the curved barbs of Suyker for any other configuration of barbs, because they are capable of performing equally as well as any other shaped barbs, and also have a hemostatic profile, and can be used over an extended range of body duct diameters. This is why the curved barbs taught by Suyker et al are sufficient to reject the hemostatic profile comprising a circular base section extending to a trihedral-shaped end portion in claims 10 and 17 of the instant application. The specification of the instant application describes a curved embodiment as well as the embodiment claimed and does not specify the reasons why one would prefer one over the other.

5. **Regarding claims 10, 15, 17, and 21**, Jacobs et al in view of Suyker et al teach

the invention substantially as claimed except for failing to teach the particular shape of the barb. However, Sancoff et al teaches that a barb can be shaped with a circular base section and a conical tip (column 5, lines 5-10). Due to lack of criticality in the specification, the trihedral-shaped tip on each barb was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to a conical tip on the barb. Therefore, it would have been obvious to make the tip of the barb tri-hedral because it is capable of working equally as well as a conical shaped barb tip. Also due to lack of criticality in the specification, the angle of the tip on each barb between 0 and 10 degrees, or 5 degrees to be more specific, and was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to a conical tip on the barb. Therefore, it would have been obvious to make the tip of the barb at an angle between 0-10 degrees because it is capable of working equally as well as any other well-known barb angle.

6. **Regarding claim 13,** due to lack of criticality in the specification, expanding the sleeve to a final diameter which is greater than twice its initial diameter was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to expanding the sleeve to twice the diameter or just under twice the diameter. Therefore, it would have been obvious to state that the sleeve must expand to at least twice the diameter of its initial unexpanded diameter.

7. **Claims 11 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al (US 2001/0044637) in view of Suyker et al (US 6,485,496), further in view of Sancoff et al (US 6,682,540) and further in view of Chobotov et al

(2003/0120338).

8. **Regarding claim 11**, Jacobs et al in view of Suyker et al disclose the invention substantially as claimed above except for failing to disclose the device being made of steel. However, Chobotov et al teaches a similar device wherein the material used to make it can be steel (page 5, prargraph 65). Many stents are made of stainless steel as it will not corrode in the body. Therefore it would have been obvious to have a connecting device comprised of steel.

9. **Regarding claim 16**, Chobotov et al teaches that the length of each barb can vary within a single device (page 6, paragraph 80). This is so that the barb lengths can be of the appropriate length for the thickness of the multiple or single layers that it has to pierce through. Therefore it would have been obvious to have barbs of a shorter length at the ends than in the intermediate portion of the device, in order to prevent damage to surrounding tissues.

10. **Claims 19 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al (US 2001/0044637) in view of Suyker et al (US 6,485,496), further in view of Sancoff et al (US 6,682,540) , further in view of Chobotov et al (2003/0120338) and further in view of Berg et al (US 6,451,048).

11. Jacobs et al in view of Suyker et al teach the invention substantially as claimed except for failing to teach a method of attaching the barbs to the device. However, Berg et al teach attachment of the barbs to the device by either soldering or gluing (figures 4a and 4b, respectively). These are both well-known methods of attaching components to

make a medical device. Therefore it would have been obvious to attach the barbs to the device in this manner.

12. **Claim 18** is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldsteen et al (US 5,941,908) in view of Jacobs et al (US 2001/0044637), further in view of Sancoff et al (US 6,682,540).

13. Goldsteen et al disclose the method substantially as claimed including the steps of intubing a first end of a prosthesis in the extremity of a body duct, setting a connecting device in place by inflating a balloon catheter, intubing a second end of the prosthesis in a body duct and setting in place a second connecting device through an orifice in the prosthesis that is subsequently reclosed (col 2, lines 56-58; column 4, lines 27-47). Goldsteen et al also disclose a connecting device being a mesh sleeve that is capable of radial expansion between a minimal-diameter configuration and a stable expanded configuration (col. 2, lines 25-27; col. 4, lines 22-46 provides additional support that the mesh sleeve is capable of radial expansion between two stable diameters).

14. Goldsteen et al fail to disclose the first connection device being set into place by introducing an inflatable balloon catheter into the prosthesis by inserting it through an end of the prosthesis, but do disclose that the balloon catheter does pass through the end of the prosthesis (figs. 8 and 9 [140]). However, due to lack of criticality in the specification, inserting the inflatable balloon catheter into the prosthesis by inserting it through an end of the prosthesis was shown to solve no particular problem, serve no particular purpose, and provide no additional benefit as opposed to inserting it through

any other orifice on the prosthesis. Therefore it would have been obvious to set both connecting devices in place by inserting a balloon catheter through orifices on the prosthesis because this method is capable of expanding the first connecting device equally as well as inserting the balloon through the open end of the prosthesis.

15. Goldsteen et al further disclose radially spaced projections extending from the sleeve (fig. 5 [36]; see col. 3, lines 33-37 for additional support) but fail to disclose barbs. However, Jacobs et al teach a sleeve capable of expansion between a minimal-diameter configuration and a stable expanded configuration with a series of fixation barbs arranged in a radial configuration about the proximal and distal ends and intermediate portions of the sleeve (figure 10B), wherein the sleeve is meant to be used at either end of a graft or prosthesis to connect it to a duct or vessel within the body. Barbs on the sleeve provide a more stable connection between the device and the graft or vessel. Therefore it would have been obvious to use the sleeve of Jacobs et al with the method disclosed by Goldsteen et al.

16. Regarding the shape of the barbs, Goldsteen et al in view of Jacobs et al teach the invention substantially as claimed except for failing to teach the particular shape of the barb. However, Sancoff et al teaches that a barb can be shaped with a circular base section and a conical tip (col. 5, lines 5-10). Due to lack of criticality in the specification, the trihedral-shaped tip on each barb was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to a conical tip on the barb. Therefore, it would have been obvious to make the tip of the barb tri-hedral because it is capable of working equally as well as a conical shaped barb tip. Additional

explanation of this can be found above in reference to claims 10 and 17.

Response to Arguments

17. Applicant's request for acknowledgement of claim of priority has been considered, and addressed earlier in this response.

18. Applicant's amendments to the abstract have been reviewed and the objection to the specification regarding the abstract has been withdrawn.

19. Applicant's amendments with respect to the 35 U.S.C. 112 claim rejections have been acknowledged and the rejections have been withdrawn.

20. Applicant's arguments filed 11/20/2006 have been fully considered but they are not persuasive. Rejections of claims 10-21 are maintained, with further explanations of the same rejections accompanying the original rejections, and appearing earlier in this response.

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ASA ASA 2/15/07

GLENN K. DAWSON
PRIMARY EXAMINER